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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,566	02/19/2002	Audrey Goddard	P 2534-3	4737
9157	7590	09/27/2004	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,566

Applicant(s)

GODDARD ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-19, 21, 23, 24, 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 22 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/15/02, 7/9/02, 6/30/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED OFFICE ACTION

Applicant's election with traverse of Group II invention, claims 20-28, directed to SEQ ID NO:5, filed on 26 March 2001 is acknowledged. The traversal is on the ground(s) that both SEQ ID NO:5 and 7 are directed to variants of the same hIL-lRα native sequence. This is not found persuasive because even though SEQ ID NO:5 and 7 are related to hIL-lRα, they have different sequence structure, and a sequence search of SEQ ID NO:5 would not necessarily reveal the result anticipating SEQ ID NO:7, nor it is possible to identify the sequence search result related to SEQ ID NO:7. As such, separate searches are required for SEQ ID NO:5 and 7, which constitute undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Currently, claims 1-30 are pending, and claims 20-28 are under consideration to the extent that they read on the elected sequence, SEQ ID NO:5, thus, claims 21, 23 and 24 are withdrawn from further consideration as no SEQ ID NO:5 recited in these claims. Claims 1-19, 29 and 30 are withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:***Specification***

The specification is objected to for the following informalities, appropriate correction is required for each item:

On page 89, line 26, it is recited that "clone DNA85066 (Figure 1; SEQ ID NO:3) was cloned into ...", however, SEQ ID NO:3 is an amino acid sequence.

Claims

Claims 20 and 25 are objected to as being dependent upon a non-elected claim. The applicant is required to rewritten the claim in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1646

Claim 22 is objected to for encompassing a non-elected subject matter, SEQ ID NO:7, 10, 13, 16, 19, 21 and 25. The applicant is required to amend the claim to read only upon the elected invention.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "the IL-11p" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 is indefinite because it is unclear which DNA encodes SEQ ID NO:5.

Claim 26 is indefinite for the recitation of "a *native* amino acid sequence of ...". According to the definition in the specification, on page 6, a "native sequence hIL-1" encompasses "any *naturally occurring allelic variant* of" SEQ ID NO:5 or fragment thereof (lines 22-23). However, it is not clear what is meant by "naturally occurring", and what distinguishes a "naturally occurring" polypeptide from one that is not. For example, it is not clear if a polypeptide produced by chemical synthesis, but having the same sequence as a polypeptide isolated from a natural source would be considered to be naturally occurring. The specification does not define such, nor the structure of any *allelic variant*. The metes and bounds of the claim, therefore, cannot be determined.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 and the dependent claims 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a polypeptide of SEQ ID NO:5, does not reasonably provide enablement for claims to any “*naturally occurring allelic variant*” thereof (encompassed by “a native amino acid sequence of the IL-11p” in claim 26). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim 26 encompasses naturally occurring allelic variants of SEQ ID NO:5 (see the definition of “a native amino acid sequence” in the specification on page 6). The specification discloses merely *two* polypeptides of hIL-1Ra1, and no allelic variants of SEQ ID NO:5 meeting the limitations of these claims were ever identified or particularly described. The claim is broad because it does not require the claimed polypeptide to be identical to the disclosed sequence and because the claims have no functional limitation. Further, the specification provides no guidance or working example as to how the skilled artisan could make such an allelic variant with a desired functional property, nor how to use an inactive allelic variant of SEQ ID NO:5, as no functional limitation associated with the variants in the claims. Therefore, it would require undue experimentation in order to make and use the claimed invention in its full scope.

Due to the large quantity of experimentation necessary to determine how to make a functional allelic variant, and how to use an allelic variant without functional activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the lack of predictability of a functional variant, and the breadth of the claims which embrace inactive allelic variant of SEQ ID NO:5, undue experimentation would be required of the skilled artisan to make and use the invention commensurate in scope with the claims

Art Unit: 1646

Claims 26-28 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass “naturally occurring allelic variants” of SEQ ID NO:5. The specification merely discloses *two* polypeptides of hIL-1Ra1, and no allelic variant of SEQ ID NO:5 meeting the limitations of these claims was ever identified or particularly described.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NO:5, a skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides of the allelic variants. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides of SEQ ID NO:5, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections Over Prior Art:

Art Unit: 1646

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20, 22 and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Timans, US6,680,380.

Timans discloses a human polypeptide of an IL-1 like molecule, which amino acid sequence (SEQ ID NO:4) comprises amino acids 35-203 of the present SEQ ID NO:5 with 100% sequence identity (see appended computer printout of sequence search results). The reference, therefore, anticipates claims 20, 22 and 25 as being a polypeptide comprising amino acid residues from about 37-203 of SEQ ID NO:5. Additionally, Timans teaches a fusion protein comprising the polypeptide and detection or purification tag including a FLAG, His6, or Ig sequence (column 3, lines 44-47). As such, the reference also anticipates claims 26-28.

Claims 20, 22 and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al., US2003/0091532 A1.

Art Unit: 1646

Sims discloses a human IL-1 related polypeptide, which amino acid sequence (SEQ ID NO:3) comprises amino acids 33-203 of the present SEQ ID NO:5 with 100% sequence identity (see appended computer printout of sequence search results). The reference, therefore, anticipates claims 20, 22 and 25 as being a polypeptide comprising amino acid residues from about 37-203 of SEQ ID NO:5. Additionally, Sims teaches a fusion protein comprising the polypeptide and Fc of an antibody ([0087] on page 12). As such, the reference also anticipates claims 26-28.

Conclusion:

No claim is allowed.

Art Unit: 1646

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
9/8/04